IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA LTD.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 15-424-LPS
	:	
SUNOVION PHARMACEUTICALS INC.,	:	
	:	
Defendants.	:	
	:	

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MEMORANDUM OPINION

March 30, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

I. INTRODUCTION

Plaintiff Cipla Ltd. ("Plaintiff") filed a patent infringement suit against Sunovian Pharmaceuticals, Inc. ("Defendant") on May 26, 2015, alleging infringement of U.S. Patent No. RE 43,984 (the '984 patent).[1] (D.I. 1) The complaint alleges direct, induced, contributory, and willful infringement. (*Id.*) On July 20, 2015, Defendant filed a motion to dismiss Plaintiff's claims for induced, contributory, and willful infringement for failure to state a claim. (D.I. 9) For the reasons that follow, the Court will deny Defendant's motion.

II. BACKGROUND[2]

Cipla Ltd. is a corporation organized under the laws of India. (D.I. 1 ¶ 2) The '984 patent, entitled "Process for Preparing Isomers of Salbutamol," was issued by the PTO on February 5, 2013. (*Id.* at ¶ 8) The patent generally relates to processes for making optically pure (R) and (S) salbutamol. ('984 patent at Abstract) The patent contains 19 claims. (7:41-8:66) The first 8 claims disclose processes for making optically pure (R) salbutamol and the remaining 11 claims disclose a series of chemical compounds. (*Id.*) Claim 9 of the '984 patent discloses "[p]ure and isolated Levalbuterol L-tartrate having an enantiomeric excess of at least 95%." (8:20-21)

Defendant holds New Drug Application No. 21-730 for Xopenex HFA Inhalation Aerosol. (D.I. 1 ¶ 9) Xopenex HFA contains levalbuterol tartrate (in at least 95% enantiomeric

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[1]The '984 patent is attached to the complaint as Exhibit A.

[2]This recitation is based, as it must be at this stage, on taking as true all well-pleaded factual allegations in the complaint.

excess) as its active pharmaceutical ingredient. (*Id.*) Defendant obtained FDA approval for Xopenex HFA on March 11, 2005. (*Id.*) Sometime after that date, Defendant began manufacturing, importing, using, selling, and/or offering Xopenex HFA in the United States. (*Id.* ¶ 12)

III. LEGAL STANDARDS

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

However, "[t]o survive a motion to dismiss, a civil plaintiff must allege facts that 'raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).'" *Victaulic Co. v. Tieman*, 499 F.3d 227, 234 (3d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element" of a plaintiff's claim. *Wilkerson v. New Media*

Tech. Charter Sch. Inc., 522 F.3d 315, 321 (3d Cir. 2008) (internal quotation marks omitted). When evaluating a complaint, the Court may consider any documents or exhibits attached to or associated with the complaint. *See* Fed. R. Civ. P. 10(c); *see also Pension Benefit Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993).

The Court is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

IV. DISCUSSION

A. Induced Infringement

In order to state a claim for induced infringement, a plaintiff must allege facts showing that: (1) the plaintiff's patent is directly infringed, (2) the defendant induced that infringement – meaning that the defendant "aided and abetted another's direct infringement of the patent," *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1306 (Fed. Cir. 1999), and (3) the defendant possessed the specific intent to encourage the third party to infringe. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003); *see also MONEC Holding AG v. Motorola Mobility, Inc.*, 897 F.Supp 2d 225, 230 (D. Del. 2012). The complaint alleges sufficient facts to meet these three requirements.

First, the complaint alleges facts that give rise to a reasonable inference that users of Xopenex HFA directly infringe the '984 patent. (*See* D.I. 1 ¶¶ 9, 25) Second, the complaint alleges facts that give rise to a reasonable inference that Defendant's actions induced third parties

to infringe – it alleges that Defendant sells and offers to sell Xopenex HFA to consumers, who it can be reasonably inferred will then use Xopenex HFA. (*See id.* ¶15) Third, the complaint adequately alleges that Defendant possessed the specific intent to encourage third parties to infringe, as it adequately alleges that Defendant knew or should have known that its actions would induce actual infringement.[3] *See DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006). Because the patented compound is (allegedly) the only active ingredient in Xopenex HFA (*see* D.I. 1 ¶ 9), one can reasonably infer that any use of Xopenex HFA will constitute infringement. Accordingly, the complaint adequately alleges that Defendant knew or should have known that its sales and offering for sale of Xopenex HFA would induce actual infringement. This conclusion is further supported by the alleged facts that Defendant sought and obtained FDA approval for Xopenex HFA and that the prescribing information for the drug instructs consumers to use the drug in a way that allegedly infringes the patent (*see id.* ¶ 10). *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1058 (indicating that labels or instructions teaching third parties how to use drug in infringing manner can be evidence of intent to induce infringement); *see also Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1322 (Fed. Cir. 2009) ("Evidence of active steps taken to induce infringement, such as advertising an infringing use, can support a finding of an intention for the product to be used in an infringing manner.").

[3]The Court interprets Plaintiff's complaint to allege induced infringement only after the date the '984 patent issued.

B. Contributory Infringement

In order to state a claim for contributory infringement, Plaintiff must allege facts to show that: (1) Defendant sold or offered to sell a material or apparatus used in practicing the patent, (2) the material or apparatus constitutes a material part of the invention and has no substantial non-infringing uses, and (3) Defendant knew that the material or apparatus was especially made or adapted for use in a way that would infringe the patent. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 850-51 (Fed. Cir. 2010). The complaint adequately alleges each of these requirements.

Again, taking as true that the '984 patent claims the active ingredient in Xopenex HFA, it follows that Plaintiff has adequately alleged that Defendant sold a product used in practicing the patent (i.e., Xopenex HFA), that Xopenex HFA has no substantial non-infringing uses, and that Defendant knew Xopenex HFA was especially made or adapted for use in a way that would infringe the patent (after the '984 patent was issued and Defendant continued to make and market Xopenex HFA without change).

The Court does not agree with Defendant that the complaint fails to allege that Defendant knew that its levalbuterol tartrate was especially made or adapted for use in a way that infringes. (*See* D.I. 10 at 9) Just because (as is undisputed) Defendant's New Drug Application was approved more than seven years before the '984 patent issued does not mean that continuing to make that product after issuance of the '984 patent cannot satisfy the made or adapted for use element. The Court interprets Plaintiff's complaint to allege contributory infringement only after the date the '984 patent issued. The requirement that a product is "especially made or adapted for use in a way that infringes" means that the product in question must infringe the patent at

issue if the product is used as intended. It does not require that the device have been originally designed with the goal of infringing a patent. *See, e.g.*, *Golden Blount, Inc. v. Robert H. Peterson Co.*, 365 F.3d 1054, 1061 (Fed. Cir. 2004).

Nor does the Court agree with Defendant's contention that the complaint fails to allege that Defendant's product has no substantial non-infringing uses. (D.I. 10 at 9-10) The complaint alleges that Defendant's "levalbuterol tartrate . . . can only be used for Xopenex HFA." (*Id.* ¶ 29)

C. Willful Infringement

In order to state a claim for willful infringement of a patent, a patent owner must allege facts to show: (1) an objectively high likelihood that the defendant's actions constituted infringement, and (2) that the defendant either knew or should have known about the risk of infringement. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007); *see also MONEC Holding AG*, 897 F. Supp. 2d at 235. Plaintiff's complaint alleges sufficient facts to meet both requirements. The complaint alleges that: the '984 patent "includes claims that recite levalbuterol tartrate with enantiomeric excess of at least 95%" (D.I. 1 ¶ 8); Defendant had (and continues to have) knowledge of the '984 patent (*id.* at ¶ 13);[4] and Defendant manufactures a product, Xopenex HFA, that contains levalbuterol tartrate in 95% enantiomeric excess (*id.* at ¶¶ 9, 11-12). The alleged fact that Xopenex HFA contains the patented compound provides the required "objectively high likelihood" of infringement, and the alleged fact that Defendant had knowledge of the patent and its claims shows that Defendant knew or should have known about the risk of infringement.

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[4]The Court interprets Plaintiff's complaint to allege willful infringement only after the date the '984 patent issued.

Defendant argues that the complaint fails to state a claim for willful infringement because it "fails to demonstrate any 'link' between its allegations regarding knowledge of the '984 patent and an infringement risk so obvious that it should have been known." (D.I. 10 at 5) (citing *Neology, Inc. v. Kapsch Trafficcom IVHS, Inc.*, 2014 WL 4675316, at *8 (D. Del. Sept, 19, 2014)) The Court agrees with Plaintiff's distinction of the case on which Defendant relies:

> Here, the Court is faced with a very different situation than *Neology*. There is no mystery as to how Defendant's actions infringed the RE '984 patent. As a pharmaceutical company, it would be obvious for Defendant to surmise that a patent claiming levalbuterol tartrate would be infringed by a commercial product that contained levalbuterol tartrate as its sole active pharmaceutical ingredient.

(D.I. 12 at 6)

V. CONCLUSION

For the reasons provided above, the Court will deny Defendants' motion to dismiss for failure to state a claim. An appropriate Order follows.